IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

BIOVAIL LABORATORIES INTERNATIONAL SRL,	:	
	:	
v.	:	05-CV-1085
	:	
IMPAX LABORATORIES, INC.	:	

ORDER ON CLAIM CONSTRUCTION

Anita B. Brody, J. **May 23 , 2006**

I. INTRODUCTION

In this patent infringement action, Plaintiff Biovail Laboratories International SRL ("Biovail") brings suit against Defendant Impax Laboratories, Inc. ("Impax") for alleged infringement of U.S. Patent No. 6,096,341 ("the '341 patent"). Biovail is the owner of the '341 patent, which involves a delayed-release formulation of the antidepressant drug bupropion hydrochloride that is marketed under the name Wellbutrin XL™. Currently before me is the question of the proper construction of the claims of the '341 patent.

II. LEGAL STANDARD

Patent infringement analysis involves two steps: (1) determining the meaning and scope of the patent claims asserted to be infringed, and (2) comparing the properly construed claims to the device accused of infringing. Markman v. Westview Instruments, Inc., 52 F.3d 967, 976 (Fed. Cir. 1995) (en banc), aff'd, 517 U.S. 370 (1996). It is the first step, known as claim construction, that is at issue here. Claim construction is a matter of law to be determined by the court. Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996).

It is a "bedrock principle" of patent law that "the claims of a patent define the invention to which the patentee is entitled the right to exclude."[1] Phillips v. AWH Corp., 415 F.3d 1303, 1312 (Fed. Cir. 2005) (citations omitted). Thus, "claim construction analysis must begin and remain centered on the claim language itself." Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc., 381 F.3d 1111, 1116 (Fed. Cir. 2004).

When a court construes a claim, the terms of a claim "are generally given their ordinary and customary meaning," that is, "the meaning that the term would have to a person of ordinary skill in the art . . . as of the effective filing date of the patent application." Phillips, 415 F.3d at 1312-13 (citations omitted). "In some cases, the ordinary meaning of claim language as understood by a person of skill in the art may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words." Id. at 1314. However, "[b]ecause the meaning of a claim term as understood by persons of skill in the art is often not immediately apparent, and because patentees frequently use terms idiosyncratically, the court looks to those sources available to the public that show what a person of skill in the art would have understood disputed claim language to mean . . . includ[ing] the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific

[1] The two main elements of a patent document are the claims and the specification, Markman, 517 U.S. at 373, the required contents of which are set forth in 35 U.S.C. § 112: "The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention. The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention." Id.

principles, the meaning of technical terms, and the state of the art." Id. (citations omitted).

"Although words in a claim are generally given their ordinary and customary meaning, a patentee may choose to be his own lexicographer and use terms in a manner other than their ordinary meaning, as long as the special definition of the term is clearly stated in the patent specification or file history." Vitronics, 90 F.3d at 1582.

"It is well-settled that, in interpreting an asserted claim, the court should look first to the intrinsic evidence of record, i.e., the patent itself, including the claims, the specification and, if in evidence, the prosecution history." Id. Extrinsic evidence, which "consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises," Phillips, 415 F.3d at 1317, "may also be considered, *if needed* to assist in determining the meaning or scope of technical terms in the claims," Vitronics, 90 F.3d at 1583 (citations omitted, emphasis in original). However, where the intrinsic evidence is sufficient to resolve any ambiguity in the claim terms at issue, "it is improper to rely on extrinsic evidence." Id.

III. DISCUSSION

The Federal Circuit has explained that in claim construction analysis, "only those terms need be construed that are in controversy, and only to the extent necessary to resolve the controversy." Vivid Tech., Inc. v. Am. Sci. & Eng'g, Inc., 200 F.3d 795, 803 (Fed. Cir. 1999). Here, the parties dispute the proper construction of four separate terms in claims 1 and 30 of the '341 patent. The relevant claims, with the disputed claim terms highlighted, are as follows:

Claim 1. A ***delayed release [tablet]***[2] comprising:

(i) a core comprising bupropion hydrochloride and conventional excipients, ***free of stabilizer***; and

(ii) a coating consisting essentially of a water-insoluble, water-permeable film-forming polymer, a plasticizer and a water-soluble polymer, where the proportion of water-insoluble, water-permeable film-forming polymer varies between 25 and 90% of the coating dry weight, the proportion of plasticizer varies between 5 and 30% of the coating dry weight, and the proportion of water-soluble polymer varies between 10 and 75% of the coating dry weight,

exhibiting a ***dissolution profile*** such that after 1 hour, from 0 up to 30% of the bupropion hydrochloride is released, after 4 hours, from 10 to 60% of the bupropion hydrochloride is released, after 6 hours, from 20 to 70% of the bupropion hydrochloride is released, after 8 hours, more than 40% of the bupropion hydrochloride is released.

Claim 30. A bupropion hydrochloride ***delayed release [tablet] free of stabilizer*** and ***free of pore-forming agent,*** exhibiting a***dissolution profile*** such that after 1 hour, from 0 up to 30% of the bupropion hydrochloride is released, after 4 hours, from 10 to 60% of the bupropion hydrochloride is released, after 6 hours, from 20 to 70% of the bupropion hydrochloride is released, after 8 hours, more than 40% of the bupropion hydrochloride is released.

('341 patent, Col. 9, lns. 49-67 and Col. 12, lns. 3-11.)

While I must come to an independent *de novo* determination of the proper meaning of each of these claim terms, I note that at least one other federal district court has already construed the claims of this very patent. In that case between Plaintiff Biovail and a different defendant involving the same patent at issue here, the District Court for the Central District of California construed three of the four claim terms disputed in this litigation. See Biovail Labs. Inc. v. Anchen Pharm. Inc., No. SACV 04-1468 (C.D. Cal. Feb. 8, 2006) (amended order on claim construction hearing). While in no way binding on me,[3] I consider the Anchen court's claim

[2] The parties disagree over whether I should construe "delayed release tablet" or only "delayed release."

[3] The parties have not argued that there is any preclusive effect or estoppel arising from the Anchen litigation.

construction decision to be persuasive authority. See V-Formation, Inc. v. Benetton Group SpA, 401 F.3d 1307, 1312 (Fed. Cir. 2005) ("The district court properly referred to a related, non-binding judicial opinion to support its independent conclusion in this case."). I turn now to the specific claim terms at issue.

A. *"Delayed Release Tablet"/"Delayed Release"*

The parties' most significant disagreement, to which they have devoted the bulk of their briefing and argument, is on the proper construction of the term "delayed release tablet" in claims 1 and 30 of the '341 patent. The central disputes between the parties over this term are: (1) whether I should construe the entire term "delayed release tablet" (Impax's position) or only "delayed release" (Biovail's position), (2) whether this claim term serves as a limitation on the scope of the claims, and (3) what its meaning is and how it limits the claimed invention.

1. "Delayed Release Tablet" vs. "Delayed Release"

As a threshold matter, I must decide whether the first claim term at issue is "delayed release tablet" or only "delayed release" – a point about which there is some disagreement between the parties. Biovail identifies "delayed release" as the relevant claim term in its opening brief and throughout its papers.[4] Impax, on the other hand, maintains that the Court must construe the entire phrase "delayed release tablet." I agree with Impax that it is necessary to construe "delayed release tablet."

First of all, I am required to construe the terms in controversy "to the extent necessary to

[4] Curiously, however, Biovail's only suggested construction of the term "delayed release" involves reference to a "tablet": "[I]f the term is construed to be a limitation, the term refers to a tablet that exhibits a dissolution profile such that after 1 hour, from 0 up to 30% of the bupropion hydrochloride is released, after 4 hours, from 10 to 60% of the bupropion hydrochloride is released . . . ." (Biovail Opening Br. at 3.)

resolve the controversy," Vivid, 200 F.3d at 803, and Biovail and Impax clearly cannot agree on a definition of "delayed release tablet." By proposing that I construe only "delayed release," Biovail seems to assume that the definition of "delayed release tablet" would flow inexorably from my construction of "delayed release." However, this is not necessarily so; it is possible that the entire phrase "delayed release tablet," as used in the '341 patent, has a meaning distinct from the sum of its component parts. The Federal Circuit has explicitly warned courts against "focus[ing] the inquiry on the abstract meaning of words rather than on the meaning of claim terms within the context of the patent." Phillips, 415 F.3d at 1321. In the context of the '341 patent, to construe "delayed release" apart from "tablet" would be to construe that phrase in the abstract rather than in its proper context. Moreover, it makes sense to keep "delayed release tablet" together for claim construction purposes because the term "delayed release tablet" is used repeatedly throughout the '341 patent, while the words "delayed release" appear only once without the word "tablet": ". . . a more *delayed release* is generally obtained with a higher amount of water-insoluble, water-permeable film-forming polymer . . ." (Col. 3, lns. 14-16 (emphasis added).) Indeed, as noted above, Biovail has not proposed any definition of "delayed release" that does not make reference to a tablet.

2. Whether to Construe "Delayed Release Tablet" as a Limitation on the Claims

As another threshold issue, I must decide whether the term "delayed release tablet" in claims 1 and 30 of the '341 patent is in fact a limitation on the claims – i.e., whether it needs to be construed at all.

Biovail asserts that because the term "delayed release tablet" resides in the "preamble" of the claims, it does not serve as a limitation on the claims and so does not require construction. In

general, patent claims are drafted with a preamble, a transitional phrase, and a body. 1 R. Carl Moy, Moy's Walker on Patents § 4:60 (4th ed. 2005) ("Walker on Patents"). The essential part of a patent claim is the body, which describes each of the invention's components, usually in the form of a list in which the various parts of the invention are set out in some sort of conceptual order. Id. § 4:58. The preamble of a patent claim consists of the words at the beginning of the claim. Id. § 4:60. It typically names the invention as falling within a generic class of objects or practices and provides a context in which to understand the specific statements of included components set out in the body. Id. The transitional phrase appears immediately after the preamble and before the body, and serves to connect the generic language of the preamble to the specific invention components set forth in the body. Id. § 4:59. Examples of transitional phrases include "consisting of" and "comprising."[5]

While it is generally the body of a patent claim that sets forth what is and is not claimed in the patented invention, language in the preamble of a claim will also be considered a limitation on the claim "if it recites essential structure or steps, or if it is necessary to give life, meaning, and vitality to the claim." Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc., 289 F.3d 801, 808 (Fed. Cir. 2002) (citations omitted). However, "if the body of the claim describes a structurally complete invention such that deletion of the preamble phrase does not affect the structure or steps of the claimed invention, the preamble is generally not limiting unless there is clear reliance on the preamble during prosecution to distinguish the claimed invention from the prior art." Intirtool, Ltd. v. Texar Corp., 369 F.3d 1289, 1295 (Fed. Cir. 2004) (citations

[5] Each transitional phrase is its own term of art with specialized meanings that are not directly relevant to the patent claims at issue here. See 1 Walker on Patents § 4:58.

omitted). Put differently, unless there has been reliance on preamble language during prosecution, the preamble does not serve to limit the claim where the patentee "uses the preamble only to state a purpose or intended use for the invention." Catalina, 289 F.3d at 808.

Biovail asserts that because "delayed release tablet" is found in the preamble of claims 1 and 30, it is not limiting and should not be construed. However, as Impax points out and Biovail does not refute, "delayed release tablet" is actually found in the *body* of claim 30. In fact, as can be seen from the following chart, claim 30 does not have a preamble or a transitional phrase, but rather consists only of a body:

	Claim 1	**Claim 30**
Preamble	A delayed release tablet	[none]
Transitional Phrase	comprising	[none]
Body	(i) a core comprising bupropion hydrochloride and conventional excipients, free of stabilizer; and (ii) a coating consisting essentially of a water-insoluble, water-permeable film-forming polymer, a plasticizer and a water-soluble polymer, where the proportion of water-insoluble, water-permeable film-forming polymer varies between 25 and 90% of the coating dry weight, the proportion of plasticizer varies between 5 and 30% of the coating dry weight, and the proportion of water-soluble polymer varies between 10 and 75% of the coating dry weight, exhibiting a dissolution profile such that after 1 hour, from 0 up to 30% of the bupropion hydrochloride is released, after 4 hours, from 10 to 60% of the bupropion hydrochloride is released, after 6 hours, from 20 to 70% of the bupropion hydrochloride is released, after 8 hours, more than 40% of the bupropion hydrochloride is released.	A bupropion hydrochloride delayed release tablet free of stabilizer and free of pore-forming agent, exhibiting a dissolution profile such that after 1 hour, from 0 up to 30% of the bupropion hydrochloride is released, after 4 hours, from 10 to 60% of the bupropion hydrochloride is released, after 6 hours, from 20 to 70% of the bupropion hydrochloride is released, after 8 hours, more than 40% of the bupropion hydrochloride is released.

Thus, even if I were to agree with Biovail that "delayed release tablet" is a non-limiting part of the preamble in claim 1, I would still need to construe it in claim 30. See Catalina, 289 F.3d at

810-11 (where term was found in the preamble of one claim and in both the preamble and body of another, it would be construed as a limitation on the claim of which it formed part of the body).

While recognizing that "delayed release tablet" appears in the preamble and not the body of claim 1, Impax argues that it should nonetheless be considered a limitation on the claim language because: (1) the term recites structure that is essential to the claimed invention, (2) the Federal Circuit indicated that similar language in a related patent could be construed as a claim limitation, and (3) the patentee relied on this term during the prosecution history to define the claimed invention. I find all of Impax's arguments to have merit.

First, Impax is correct that the term "delayed release tablet" in the preamble of claim 1 recites essential structure and "is necessary to give life, meaning, and vitality to the claim." Catalina, 289 F.3d at 808 (citations omitted). Courts have found preamble language to be limiting where it "states a necessary and defining aspect of the invention," rather than merely providing "an introduction to the general field of the claim." On Demand Machine Corp. v. Ingram Indus., Inc., 442 F.3d 1331, 1343 (Fed. Cir. 2006). As Impax observes, "delayed release tablet" provides the essential structure for claim 1 because it is the only term that limits the invention described in claim 1 to a *tablet* and not, for instance, a "capsule filled with microspheres that met the other structural limitations of claim 1."[6] (Impax Opening Br. at 29.) Thus, this is not a case where "deletion of the preamble phrase does not affect the structure or steps of the claimed invention." Intirtool, 369 F.3d at 1295. Deleting "delayed release tablet"

[6] I recognize that "delayed release" could possibly be deleted from claim 1 without rendering the claim meaningless. However, as noted above, I find it necessary to construe the term "delayed release tablet" and not just "delayed release."

from claim 1 would not only eliminate the invention's tablet structure, it would deprive the tablet of its fundamental characteristic, which is its delayed release. See Poly-America, L.P. v. GSE Lining Tech., Inc. 383 F.3d 1303, 1310 (Fed. Cir. 2004) (preamble language that states "fundamental characteristic of the claimed invention" is "properly construed as a limitation of the claim itself").

In addition, Impax points out that in two infringement cases involving U.S. Patent No. 5,427,798 ("the '798 patent"), which involves a "controlled sustained release" formulation of bupropion hydrochloride, the Federal Circuit indicated that the term "sustained release tablet" in the preamble of one of the claims could be read as a claim limitation. Glaxo Wellcome, Inc. v. Impax Labs., Inc., 356 F.3d 1348, 1353 (Fed. Cir. 2004) ("The 'sustained release tablet' phrase recited in the preamble gives life and meaning to the claims, because sustained release is an essential feature of the invention."); see also SmithKline Beecham Corp. v. Excel Pharm., Inc., 356 F.3d 1357, 1362-63 (Fed. Cir. 2004). Because the Federal Circuit did not explicitly construe the term "sustained release tablet" in the '798 patent in these cases, they are not controlling here. However, I cannot ignore the fact that the Federal Circuit, in considered dicta, stated that a term very similar to "delayed release" in a patent very similar to the '341 patent was a limitation on the claimed invention, despite being in a claim's preamble. These highly persuasive decisions of the Federal Circuit further confirm that "delayed release" in the preamble of claim 1 should be construed as a limitation on the claim.

Finally, Impax observes that the patentee specifically relied on the phrase "delayed release" in the preamble of claim 1 during the prosecution history of the '341 patent. In Application 09/184,091 ("the '091 application"), the patent application that led to the '341

patent, claim 1 originally read "[a] *controlled* release tablet comprising . . . " and claim 30 read "[a] bupropion hydrochloride *controlled* release tablet . . . ."[7] (Prosecution History at BV 76746, 76749 (emphasis added) (hereinafter "Prosec. Hist.").) In April 1999, the United States Patent and Trademark Office (USPTO) examiner issued an Office Action that rejected all of the patentee's claims. (Id. at BV 76756-64.) Among the rejections was one for "obviousness-type double patenting."[8] (Id. at BV 76758-59.) In the April 1999 Office Action, the USPTO examiner stated:

> Claims 1-35 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-35 of copending Application No. 09/184096. Although the claims are not identical, they are not patentably distinct from each other because the dissolution rates are essentially the same, the only difference being in the wording.

(Prosec. Hist. at BV 76758-59.) Application 09/184096 ("the '096 application"), which ultimately issued as U.S. Patent No. 6,033,686 ("the '686 patent"), was another patent application by the inventor of the '341 patent, Pawan Seth. The '091 and '096 applications were filed simultaneously, and the '096 application also claimed a "controlled release" formulation of a bupropion hydrochloride tablet. (Prosec. Hist. at BV 76811.)

In August 1999, in direct response to this Office Action, the patentee filed an Amendment to his application in which, *inter alia*, the words "controlled release" in claims 1 and 30 were

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[7] Citations to the prosecution history of the '341 patent are to Bates-numbered pages in the certified copy that Biovail submitted to the Court.

[8] Under the doctrine of obviousness-type double patenting, "a patent is invalid when it is merely an obvious variation of an invention disclosed and claimed in an earlier patent by the same inventor." Georgia-Pacific Corp. v. U.S. Gypsum Co., 195 F.3d 1322, 1326 (Fed. Cir. 1999). The doctrine is "designed to achieve two purposes: (i) to prevent the second patent from extending the length of the patent term, and (ii) to shield competitors from the risk of multiple, inconsistent suits for infringement." 1 Walker on Patents § 3:67.

changed to "delayed release." (Prosec. Hist. at BV 76808-10.) In a section entitled "Double Patenting Rejection," the patentee explained the reason for this particular amendment:

> This application [the application that led to the '341 patent] and commonly assigned U.S. Serial No. 09/184,096 filed October 30, 1998 are distinct from each other, because they are directed to two distinct release profiles.
>
> U.S. Serial No. 09/184,096 deals with a bupropion tablet having a controlled release profile as set forth in independent Claims 1, 26, 28 and 30. The tablet exhibits a dissolution profile such that after 1 hour, from 30 to 60% of the bupropion hydrochloride is released, after 2 hours, from 55 to 80% of the bupropion hydrochloride is released, after 3 hours, from 75 to 95% of the bupropion hydrochloride is released, after 4 hours, from 80 to 100% of the bupropion hydrochloride is released.
>
> This application, U.S. Serial No. 09/184,091, deals with a bupropion tablet having a delayed release profile as set forth in independent Claims 1, 26, 28 and 30. The tablet exhibits a dissolution profile such that after 1 hour, up to 30% of the bupropion hydrochloride is released, after 4 hours, from 10 to 60% of the bupropion hydrochloride is released, after 6 hours, from 20 to 70% of the bupropion hydrochloride is released, after 8 hours, more than 40% of the bupropion hydrochloride is released.

(Id. at BV 76811-12 (emphasis in original).) Thus, the patentee specifically relied on a distinction between "delayed" and "controlled" release in the preamble of claim 1 and the body of claim 30 to attempt to avoid the examiner's double patenting rejection over the '096 application.

"[C]lear reliance on the preamble during prosecution to distinguish the claimed invention from the prior art transforms the preamble into a claim limitation because such reliance indicates use of the preamble to define, in part, the claimed invention." Catalina, 289 F.3d at 808; see also Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings, 370 F.3d 1354, 1362 (Fed. Cir. 2004), cert. granted in part on other grounds, ___ U.S. ___, 126 S. Ct. 601 (2005) ("A preamble may provide context for claim construction, particularly, where as here, that preamble's statement of intended use forms the basis for distinguishing the prior art in the patent's prosecution history."). Here, by

specifically changing "controlled release" to "delayed release" in the preamble of claim 1 in response to the PTO's action, the patentee engaged in "use of the preamble to define, in part, the claimed invention." Catalina, 289 F.3d at 808.

Biovail counters by noting that the patent examiner did not ultimately accept the patentee's basis for distinguishing the '096 application, but instead required the patentee to file a "terminal disclaimer" of the '096 application in order to obtain the '341 patent.[9] In this terminal disclaimer, the patentee disclaimed "the terminal part of [the '341 patent] which would extend beyond the expiration date of the full statutory term of any United States Patent that may issue based upon [the '096 application]." (Prosec. Hist. at BV 76818.) The patentee further agreed that the '341 patent would be enforceable "only for and during such period that the legal title to said patent shall be the same as the legal title to any U.S. patent which may issue based upon [the '096 application]." (Id.) However, the fact that the examiner did not ultimately go along with the patentee does not change the fact that the patentee relied on the phrase "delayed release tablet" in the preamble "to define, in part, the claimed invention." Catalina, 289 F.3d at 808. Clearly, the patentee saw this preamble language as a limitation on the claims, or he would not have altered it an attempt to clarify the scope of the claims. Thus, it can properly "provide context for claim construction." Metabolite, 370 F.3d at 1362.

3. The Meaning of "Delayed Release Tablet," as Used in the '341 Patent, to a Person of Ordinary Skill in the Art

In addition to disputing whether "delayed release tablet" must be construed at all, the

[9] A terminal disclaimer is a document by which a patentee "disclaim[s] or dedicate[s] to the public the entire term, or any terminal part of the term, of a patent to be granted," 37 C.F.R. § 1.321(b), and is a common way of avoiding an obviousness-type double patenting rejection, 1 Walker on Patents § 3:67.

parties disagree on the proper construction of the term in claims 1 and 30 of the '341 patent. Biovail asserts that "delayed release tablet" is defined solely with respect to the particular dissolution profile exhibited by the tablet:

> a tablet that exhibits a dissolution profile such that after 1 hour, up to 30% of the bupropion hydrochloride is released, after 4 hours, from 10 to 60% of the bupropion hydrochloride is released, after 6 hours, from 20 to 70% of the bupropion hydrochloride is released, after 8 hours, more than 40% of the bupropion hydrochloride is released.[10]

(Biovail Opening Br. at 3.) Impax, on the other hand, claims that "delayed release tablet" means

> a tablet comprising a core which includes bupropion hydrochloride and conventional excipients and a coating designed to achieve a controlled release of bupropion hydrochloride, said coating comprising a water-insoluble, water-permeable film-forming polymer, together with a plasticizer and a water-soluble polymer.

(Impax Opening Br. at 9-10.) The crux of the dispute over this term is thus whether "delayed release tablet" means any tablet with the dissolution profile described in claims 1 and 30 or, more narrowly, "a tablet with specific components and a coating that controls the release of the active ingredient." (Impax Opening Br. at 9.) I ultimately conclude that Impax prevails on this issue.

When a court construes a patent claim, the presumption is that each claim term has its "ordinary and customary meaning," in other words, "the meaning that the term would have to a person of ordinary skill in the art . . . as of the effective filing date of the patent application." Phillips, 415 F.3d at 1313 (citations omitted). Here, there does not appear to be much dispute between the parties as to the "ordinary and accustomed meaning" of "delayed release." The experts retained by the parties agree that in general, one skilled in the art would understand a

[10] I note that because both claim 1 and claim 30 explicitly limit the claimed invention to a tablet having this dissolution profile, Biovail's proposed construction of "delayed release tablet" would not seem to add any additional limitations to the claims.

"delayed release tablet" to be any tablet that does not release its active ingredient immediately. (Biovail Supplemental Br. Ex. 1, Dep. of Arthur H. Kibbe, Ph.D. at 106; Ex. 2., Dep. of Robert O. Williams, III, Ph.D. at 58.) However, the fact that "delayed release" has a generally accepted meaning in the art does not necessarily mean that the patentee intended "delayed release tablet" as used in the '341 patent to incorporate this definition. "Although words in a claim are generally given their ordinary and customary meaning, a patentee may choose to be his own lexicographer and use terms in a manner other than their ordinary meaning, as long as the special definition of the term is clearly stated in the patent specification or file history." Vitronics, 90 F.3d at 1582. Moreover, "a claim term may be clearly redefined without an explicit statement of redefinition." Bell Atlantic Network Serv., Inc. v. Covad Communications Group, Inc., 262 F.3d 1258, 1268 (Fed. Cir. 2001). In this case, both parties agree that the patentee acted as his own lexicographer to give the term "delayed release tablet" a meaning different from its ordinary and accustomed one; however, they disagree on what that meaning is.

As already mentioned, Impax asserts that the patentee defines "delayed release tablet" in the specification of the '341 patent to mean a tablet comprising a core and a coating with specific ingredients, in which the coating controls the release of the drug. Biovail, on the other hand, claims that the patentee defined the term more broadly in the course of the '341 patent's prosecution history, and that it encompasses any tablet that achieves the dissolution profile stated in claims 1 and 30. The parties' different definitions of "delayed release tablet" are ultimately immaterial in claim 1, because that claim already recites a tablet having a core and a coating. However, Impax's proposed construction would also limit claim 30 to a tablet in which a coating controls the release of the active ingredient, while Biovail's construction would allow claim 30 to

cover any bupropion hydrochloride tablet with the specified dissolution profile, with or without a coating, provided that the tablet was free of stabilizer and pore-forming agent. Thus, the parties' ultimate dispute over the definition of "delayed release tablet" is whether, as Biovail contends, the term "delayed release tablet" in claim 30 can be construed to cover bupropion hydrochloride tablets in which the release is controlled other than by a special coating. Resolving this dispute requires an inquiry into the essence of the invention disclosed in the '341 patent.

The proper construction of "delayed release tablet" is a close question, and both parties' positions were ably presented in their briefs and at oral argument. However, Impax's proposed construction is ultimately the correct one because the Federal Circuit has made it clear that "the claims cannot be of broader scope than the invention that is set forth in the specification." On Demand, 442 F.3d at 1340. As discussed further below, because the '341 patent, as set forth in the specification, does not teach any means of controlling the release of bupropion hydrochloride other than by a special coating, I cannot construe the patent to cover tablets in which the release is not controlled by a coating, as Biovail requests. Because Impax's proposed construction of "delayed release tablet" is "[t]he construction that stays true to the claim language and most naturally aligns with the patent's description of the invention," Phillips, 415 F.3d at 1316 (citations omitted), it is the construction that I adopt.

a) Impax's Proposed Construction

Because "claim construction analysis must begin and remain centered on the claim language itself," Innova, 381 F.3d at 1116, I look first to the claims of the '341 patent. The claim language supports Impax's proposed construction of "delayed release tablet," which would limit the claimed invention to a tablet having both a core and a coating. See Phillips, 415 F.3d at 1314

("[T]he claims themselves provide substantial guidance as to the meaning of particular claim terms . . . . To begin with, the context in which a term is used in the asserted claim can be highly instructive."). Claim 30 states that the delayed release tablet of the invention is to be free of "pore-forming agent." (Col. 12, line 4.) While the parties disagree as to the exact definition of pore-forming agent, both parties agree that it is a substance "capable of being eluted from a coating." (Biovail Opening Br. at 3; Impax Opening Br. at 35.) As Impax points out, there would be little reason to mention a substance that can be "eluted from a coating" in claim 30 unless that claim was understood to require a coating. Thus, the claim language itself indicates that "delayed release tablet" should be construed to limit claim 30 to a tablet in which the coating controls the release of the drug.

Standing alone, the claim language might not compel Impax's construction; however, as explained fully below, when read in light of the specification, the claim language necessarily limits the claimed invention to a tablet in which a special coating controls the release of the active ingredient. This is dispositive of the construction of "delayed release tablet," because in addition to being "the single best guide to the meaning of a disputed term," Phillips, 415 F.3d at 1315 (citing Vitronics, 90 F.3d at 1582), the specification also serves as the "the scope and outer boundary of claims," On Demand, 442 F.3d at 1338.

In its *en banc* decision in Phillips, the Federal Circuit considered "the extent to which [courts] should resort to and rely on a patent's specification in seeking to ascertain the proper scope of its claims." 415 F.3d at 1312. Observing that it had "long emphasized the importance of the specification in claim construction," the court reaffirmed this importance, noting that it "derives from . . . the statutory requirement that the specification describe the claimed invention

in 'full, clear, concise, and exact terms.' " Id. at 1315-16; see also Autogiro Co. of Am. v. United States, 384 F.2d 391, 397-98 (Ct. Cl. 1967) (specification acts as a "concordance for the claims"); Standard Oil Co. v. Am. Cyanamid Co., 774 F.2d 448, 452 (Fed. Cir. 1985) (specification is "the primary basis for construing the claims"); Markman, 52 F.3d at 979 (claims "must be read in view of the specification, of which they are a part"); Network, LLC v. Centraal Corp., 242 F.3d 1347, 1352 (Fed. Cir. 2001) ("The claims are directed to the invention that is described in the specification; they do not have meaning removed from the context from which they arose."). Thus, the Federal Circuit concluded that it is "entirely appropriate for a court, when conducting claim construction, to rely heavily on the written description for guidance as to the meaning of the claims." Phillips, 415 F.3d at 1317.

Subsequently, the Federal Circuit gave further content to this principle in On Demand. That case involved a patent for a system of printing and binding a single copy of a book, generally at the point of sale, after providing the customer with computerized information about the book. 442 F.3d at 1334. The defendants accused of infringing this process included printing companies that printed single copies of books for wholesalers and retailers, but did not sell to retail consumers directly. Id. at 1335. The defendants disputed, *inter alia*, the district court's construction of claim 8 of the patent, which claimed "[a] method of high speed manufacture of a single copy of a book" comprising certain steps, including "storing sales information relating to . . . books in a computer" and "providing means for a customer to visually review said sales information." Id. at 1336. The district court construed the term "customer" to include not only retail customers but anyone who buys goods and services, and construed "sales information" to include any data stored in a computer involved in the promoting and selling of a book, including

price, title, and ISBN number. Id. at 1338-39. So construed, the patent was found infringed. Id. at 1336.

On appeal, the Federal Circuit found the district court's claim construction to have been erroneous and reversed. At the outset, the On Demand court noted that Phillips had "stressed the dominance of the specification in understanding the scope and defining the limits of the terms used in the claim." Id. at 1337-38. The court went on to state that "the role of the specification is to describe and enable the invention. In turn, the claims cannot be of broader scope than the invention that is set forth in the specification." Id. at 1340. Turning to the claim terms at issue, the court found that the patent's specification indicated that "customer" was meant to include only end retail consumers, not retailers and wholesalers of books, and that the district court had erred in construing the term otherwise. Id. at 1340. Similarly, the court found that "[t]he specification makes clear that sales information is that which would help the consumer to choose a book," such as the book's synopsis and critical reviews, and thus the district court's construction, insofar as it also encompassed basic information such as title and ISBN number, was broader than the specification allowed. Id. at 1338.

In the present case, as in On Demand, the specification of the patent at issue serves as the "outer boundary" of the claims. To the extent that Biovail's proposed construction of "delayed release tablet" would encompass tablets in which something other than a special coating controls the release of the active ingredient, Biovail's construction is broader than the specification of the '341 patent allows and must be rejected in favor of Impax's.

Impax cites numerous sections of the '341 patent's specification indicating that a coating is an integral part of the invention. Looking at the specification as a whole, it becomes evident

that the essence of the invention disclosed in the '341 patent is, as Impax claims, a tablet with both a core and a coating in which the coating controls the release of the active ingredient. On the very first page of the '341 patent, the abstract[11] provides:

> The invention provides a controlled release tablet, free of stabilizer and free of pore-forming agent comprising: (i) *a core* consisting essentially of bupropion hydrochloride, a binder and a lubricant; *and* (ii) *a coating* consisting essentially of a water-insoluble, water-permeable film-forming polymer, a plasticizer and a water-soluble polymer.

('341 patent, abstract (emphasis added).) On the next page, the Summary of the Invention[12] repeats the abstract verbatim (col. 1, lns. 46-52) and goes on to state that "the controlled release is obtained *thanks to a semi-permeable release coating*" (id. lns. 56-58). Thereafter, the Detailed Description of the Invention[13] provides that "[t]he invention consists in a tablet *comprising a core and a coating*" (id. lns. 66-67) and that "[t]hese tablet cores are then coated with *the semi-permeable coating designed to achieve a controlled release of bupropion hydrochloride*" (col. 2, lns. 50-53) (emphasis added). Finally, Impax points out that in each of the Best Modes of

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[11] "The purpose of the abstract is to enable the United States Patent and Trademark Office and the public generally to determine quickly from a cursory inspection the nature and gist of the technical disclosure." USPTO, Manual of Patent Examining Procedure 608.01(b) (8th ed. 2005) (hereinafter "MPEP") (quoting 37 C.F.R. § 1.72).

[12] "A brief summary of the invention indicating its nature and substance, which may include a statement of the object of the invention, should precede the detailed description. *Such summary should, when set forth, be commensurate with the invention as claimed* and any object recited should be that of the invention as claimed. Since the purpose of the brief summary of invention is to apprise the public, and more especially those interested in the particular art to which the invention relates, of the nature of the invention, *the summary should be directed to the specific invention being claimed . . . .*" MPEP § 608.01(d) (quoting 37 C.F.R. § 1.73) (emphasis added).

[13] "The specification must set forth *the precise invention for which a patent is solicited*, in such manner as to distinguish it from other inventions and from what is old." 37 C.F.R. § 1.71(b) (emphasis added).

Practicing the Invention,[14] it is the coating of the tablet that controls the release of bupropion hydrochloride.[15] "[W]hile it is of course improper to limit the claims to the particular preferred embodiments described in the specification, the patentee's choice of preferred embodiments can shed light on the intended scope of the claims." Astrazeneca AB v. Mut. Pharm. Co., 384 F.3d 1333, 1340 (Fed. Cir. 2004). In short, the specification of the '341 patent establishes that the essence of the invention disclosed is a tablet in which release of the active ingredient is controlled by a coating.[16]

"Where the specification makes clear that the invention does not include a particular feature, that feature is deemed to be outside the reach of the claims of the patent, even though the language of the claims, read without reference to the specification, might be considered broad enough to encompass the feature in question." Inpro II Licensing, S.A.R.L. v. T-Mobile USA, Inc., ___ F.3d ___, 2006 WL 1277815, at *3 (Fed. Cir. May 11, 2006) (quoting SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc., 242 F.3d 1337, 1341 (Fed. Cir. 2001)); see also Boss Control, Inc. v. Bombardier Inc., 410 F.3d 1372, 1379 (Fed. Cir. 2005) ("Because the

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[14] "The best mode contemplated by the inventor of carrying out his or her invention must be set forth in the description." MPEP § 608.01(h) (citing 35 U.S.C. § 112). Compliance with the best mode requirement requires disclosing the inventor's "preferred embodiment" of the claimed invention. Bayer AG v. Schein Pharm., Inc., 301 F.3d 1306, 1316 (Fed. Cir. 2002).

[15] Biovail claims that in Examples 6-9, ingredients in the core may *contribute* to the rate of release of the active ingredient. However, Biovail does not contend that in any of these embodiments it is the core that is *controlling* the release of the drug.

[16] In its briefs and at oral argument, Impax also pointed to certain extrinsic evidence (such as the deposition testimony of Biovail's expert and the inventor, and Biovail's statements in related patent litigation) that, according to Impax, reflect a general consensus that the '341 patent discloses a tablet with a core and a coating in which the coating controls the release of the drug. While not entitled to as much weight as the intrinsic evidence, this extrinsic evidence confirms the conclusion I have reached by looking at the claim language and the specification.

specification makes clear that the invention involves a two-stage interrupt mode, the intrinsic evidence binds Boss to a narrower definition of 'interrupt' than the extrinsic evidence might support."). Here, the specification of the '341 patent makes clear that the tablet of the invention does not include any means for controlling the release of the drug other than a specialized coating. Thus, I cannot adopt a construction of "delayed release tablet" that would encompass such technology, even though the term "delayed release tablet" might admit of such a definition if construed in the abstract.

In opposition to Impax's proposed construction, Biovail argues that: (1) it impermissibly imports limitations from the specification into the claims, one of the "cardinal sins" of claim construction, Phillips, 415 F.3d at 1320, and (2) it would give claims 1 and 30 essentially the same scope, thus violating the doctrine of "claim differentiation" under which different claims of a patent are presumed to have different scope, see Curtiss-Wright Flow Control Corp. v. Velan, Inc., 438 F.3d 1374, 1380 (Fed. Cir. 2006). Both of these arguments fail.

First of all, there is a difference between reading a limitation from the specification into the claims, which is improper, and reading the claims "in view of the specification, of which they are a part," Markman, 52 F.3d at 979, which is not only proper but required. The Federal Circuit has observed that while "the distinction between using the specification to interpret the meaning of a claim and importing limitations from the specification into the claim can be a difficult one to apply in practice . . . the line between construing terms and importing limitations can be discerned with reasonable certainty and predictability if the court's focus remains on understanding how a person of ordinary skill in the art would understand the claim terms." Phillips, 415 F.3d at 1323.

Here, when read in light of the specification, it is clear that "delayed release tablet" must be construed to require a core and a coating that controls the release of the drug. This is not importing a limitation from the specification into the claims, but rather viewing the claims in the way that a person of ordinary skill would, mindful that the specification constitutes "the scope and outer boundary" of the claims. On Demand, 442 F.3d at 1338. To see how this analysis falls on the proper side of the line between interpretation and importation, it is instructive to compare this case with SciMed Life Systems, Inc. v. Advanced Cardiovascular Systems, Inc., 242 F.3d 1337 (Fed. Cir. 2001).

SciMed involved a patent for a balloon dilation catheter used in coronary angioplasty. Id. at 1338. Catheters contain tubular passageways called "lumens," and two configurations of lumens are known in the art: dual (or adjacent), in which lumens are positioned side by side within the catheter, and coaxial, in which one lumen is placed inside the other. Id. at 1339. Just as in this case I conclude that the specification limits the '341 patent to a tablet in which the coating controls release of the drug, in SciMed, the Federal Circuit held that the specification of a patent for a catheter limited the claimed invention to a "coaxial" type of catheter. Id. at 1339. In SciMed, the abstract and summary of the invention sections of the patent contained language indicating that the catheter's tubes were placed inside one another in a coaxial configuration. Id. at 1342-43. Similarly, in present case, the abstract of the '341 patent refers to a tablet comprising both a core and a coating and the written description repeatedly attributes control of the release of the drug to the tablet's semi-permeable coating. In SciMed, the patent's specification contained a discussion of the disadvantages of dual lumen catheters, which was considered evidence that the patentee disclaimed that technology in favor of a coaxial configuration. Id. at 1342-43.

Likewise, the specification of the '341 patent discusses the disadvantages of "matrix technology," which is a method for controlling the release of the active ingredient that involves the core rather than the coating. (Impax Opening Br. Ex. C at 9, Expert Report of Arthur H. Kibbe, Ph.D.) The specification ultimately concludes that "[m]atrix technology is however not suited for the manufacture of a tablet, since it implies the use of a stabilizer" (col. 1, lns. 24-26), further indicating that it is the coating and not the core of the tablet that controls release of the drug in the '341 patent. The plaintiff in SciMed argued, much as Biovail argues here, that limitations from the written description or preferred embodiments of the invention must not be read into the claims. However, the Federal Circuit found that this was "not an accurate characterization of what the district court did. Instead, the district court properly followed the invocation that claims must be read in view of the specification, of which they are a part." Id. at 1340 (citations omitted). Similarly, I reject Biovail's argument.

As stated earlier, Biovail also argues that Impax's proposed construction would violate the doctrine of claim differentiation, which is the "presumption that each claim in a patent has a different scope." Curtiss-Wright, 438 F.3d at 1380. Biovail claims that Impax's proposed construction gives claims 1 and 30 essentially the same scope because it limits them both to a tablet comprising a core and a coating with specific components that exhibits a certain dissolution profile. First of all, the Federal Circuit has recognized that claim differentiation is most relevant when a party tries to give the same meaning to a dependent claim and the independent claim on which it depends. Id. That is not the case here, because claims 1 and 30

are both independent claims in that they do not depend on any other claim for their meaning.[17] Moreover, as Impax notes and Biovail does not refute, claims 1 and 30 would still have a different scope even with Impax's proposed construction of "delayed release tablet": claim 1 would recite a tablet with a core and a coating containing specific proportions of certain ingredients, while claim 30 would recite a tablet wherein the components of the core need not be in any particular proportions. Where there is any difference in scope between two claims, claim differentiation loses its force as an analytical tool. See, e.g., Creo Prods. v. Presstek, Inc., 305 F.3d 1337, 1349-50 (Fed. Cir. 2002); Telemac Cellular Corp. v. Topp Telecom, Inc., 247 F.3d 1316, 1325-26 (Fed. Cir. 2001). Thus, Biovail's claim differentiation argument is rejected.

b) Biovail's proposed construction

Biovail essentially relies on the prosecution history of the '341 patent to support its proposed construction. Biovail argues that in the prosecution history (specifically the August 1999 Amendment), the patentee defined "delayed release" in contrast to "controlled release" by reference to the specific dissolution profile set forth in claims 1 and 30. As noted above, in August 1999, the inventor of the '341 patent attempted to overcome a double-patenting rejection over the '096 application by amending claims 1 and 30 of the '341 patent to recite a "delayed release" tablet as opposed to a "controlled release" tablet. Biovail argues that in doing so, the patentee tied "delayed release" to the dissolution profile in claims 1 and 30 of the '341 patent and

[17] "One or more claims may be presented in dependent form, referring back to and further limiting another claim or claims in the same application." MPEP § 608.01(n). For example, in the '341 patent, claims 2-25 are dependent claims depending on claim 1. Claim 2 claims "[t]he tablet of claim 1, where the water-insoluble, water-permeable film-forming polymer is ethylcellulose." (Col. 10, lns. 1-2.)

"controlled release" to the dissolution profile in the claims of the '096 application. Biovail thus asserts that the only limitation the term "delayed release tablet" imposes on the tablets described in claims 1 and 30 is that they have a particular dissolution profile.[18]

It is true that the patentee may act as his or her own lexicographer to define a claim term during the prosecution history, as well as in the specification. See Schoenhaus v. Genesco, Inc., 440 F.3d 1354, 1358 (Fed. Cir. 2006) (patentee may set forth special definitions of claim terms in either the patent specification or the file history). However, the Federal Circuit has consistently afforded more weight to the specification than to the prosecution history in the context of claim construction. See Phillips, 415 F.3d at 1317 ("[B]ecause the prosecution history represents an ongoing negotiation between the PTO and the applicant, rather than the final product of that negotiation, it often lacks the clarity of the specification and thus is less useful for claim construction purposes."); id. at 1315 (quoting Multiform Desiccants v. Medzam, Ltd.,133 F.3d 1473, 1478 (Fed. Cir. 1998)) ("T]he best source for understanding a technical term is the specification from which it arose, informed, *as needed*, by the prosecution history."). Here, the construction that Biovail would draw from the prosecution history is broader than the "outer boundary" set forth in the specification, in that it would encompass tablets in which something other than a coating controls the release of the drug. Thus, even assuming *arguendo* that the prosecution history does support Biovail's proposed construction, I cannot rely on the prosecution history to assign "delayed release tablet" a meaning that is broader than the specification allows. Accordingly, Biovail's construction of "delayed release tablet" must be

[18] As noted earlier, because both claim 1 and claim 30 already require this dissolution profile, Biovail's proposed limitation on the claims is not really a limitation at all.

rejected in favor of Impax's:

> A tablet comprising a core which includes bupropion hydrochloride and conventional excipients and a coating designed to achieve a controlled release of bupropion hydrochloride, said coating comprising a water-insoluble, water-permeable film-forming polymer, together with a plasticizer and a water-soluble polymer.

B. *"Free of Stabilizer"*

The parties also disagree on the proper construction of the term "free of stabilizer" in claims 1 and 30 of the '341 patent.[19] Biovail asserts that "free of stabilizer" means "that the core and tablet lack an effective stabilizing amount of an organic or inorganic acid capable of inhibiting the degradation of bupropion hydrochloride, and existing as a solid or liquid under ambient conditions." (Biovail Opening Br. at 3.) Impax claims that "free of stabilizer" means "wherein the core (claim 1) or the tablet (claim 30) is free of any substance or agent that tends to prevent changes to the chemical integrity of the tablet." (Impax Opening Br. at 31.) The central disputes between the parties over this term are: (1) whether the invention must be completely free of stabilizer (Impax's position) or need only "lack an effective stabilizing amount" of a stabilizer (Biovail's position), (2) whether the stabilizer must be either an organic or inorganic acid (Biovail's position), (3) whether the stabilizer must exist as a solid or liquid under ambient conditions (Biovail's position), and (4) whether a "stabilizer" is properly defined as a "substance or agent that tends to prevent changes to the chemical integrity of the tablet" (Impax's position).

Biovail contends that "free of stabilizer" means "lacking an *effective stabilizing amount*"

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[19] "Free of stabilizer" and "free of pore-forming agent" in the '341 patent are both "negative limitations" that define the claimed invention by what it is not. See Upsher-Smith Labs., Inc. v. Pamlab, L.L.C., 412 F.3d 1319, 1321-23 (Fed. Cir. 2005). Thus, a narrower construction of these limiting terms results in a broader construction of the claim and vice versa.

of stabilizer. This argument must be rejected. As the Central District of California recognized in the related Anchen litigation, the specification of the '341 patent explicitly provides that the invention is "free of stabilizer of any kind." (Col. 1 line 55.) The specification is "the single best guide to the meaning of a disputed term." Phillips, 415 F.3d at 1315. Biovail argues that if a stabilizer were not present in the invention in an amount sufficient to stabilize the tablet, then it would not really be acting as a "stabilizer," and the tablet would still be "free of stabilizer." While this argument may be of philosophical interest, it does not comport with the ordinary and accustomed meaning of "free of stabilizer." When construing a claim involves "application of the widely accepted meaning of commonly understood words," general purpose dictionaries may prove helpful in determining a term's ordinary and accustomed meaning. Phillips, 415 F.3d at 1314. As the Anchen court noted, there is no reason not to apply the ordinary English meaning of "free of" when construing "free of stabilizer": "not having or using"; "lacking." Webster's Third New Int'l Dict. of the English Language Unabrid. 905 (1993) (hereinafter "Webster's"). If the tablet did in fact contain a compound used for stabilizing the tablet, but simply not enough of it, one would not call it "free of stabilizer," but rather "lacking sufficient stabilizer." Nor is this a case where the patentee acted as his own lexicographer in the specification to define "free of," contrary to its ordinary and accustomed meaning, as "lacking an effective amount of." In light of the specification's clear statement that the claimed invention is "free of stabilizer of any kind," I must reject Biovail's proposed construction of "free of stabilizer."

For the same reason, I reject Biovail's arguments that "free of stabilizer" means free of stabilizers that are organic or inorganic acids and are solids or liquids under ambient conditions. Such constructions would interpret the '341 patent to cover tablets containing stabilizers that are

not organic or inorganic acids, or are not solids or liquids under ambient conditions, contrary to the specification's directive that the invention is free of stabilizer of any kind.

Because a specialized meaning for "stabilizer" in the '341 patent is not suggested by the claims, the specification, or the prosecution history, I see no reason not to construe "stabilizer" according to its ordinary and accustomed meaning. The Federal Circuit has noted that technical dictionaries can be of use to a court in determining the meaning of claim terms to one of ordinary skill in the art. See Phillips, 415 F.3d at 1318 ("We have especially noted the help that technical dictionaries may provide to a court to better understand the underlying technology and the way in which one of skill in the art might use the claim terms.") (citations omitted). Hawley's Chemical Dictionary defines "stabilizer" as "[a]ny substance that tends to keep a compound, mixture, or solution from changing its form or chemical nature." Hawley's Condensed Chemical Dictionary 1042 (13th ed. 1997) (hereinafter "Hawley's").

For these reasons, I construe "free of stabilizer" in claims 1 and 30 of the '341 patent to mean "lacking any substance or agent that tends to prevent bupropion hydrochloride from changing its form or chemical nature."

C. *"Free of Pore-Forming Agent"*

The parties also disagree on the proper construction of the term "free of pore-forming agent" in claim 30. Biovail asserts that it means "lacking a particulate monomeric water soluble species capable of being eluted from a coating to form a pore therein." (Biovail Opening Br. at 3.) Impax claims that it means "wherein the tablet lacks a monomeric water-soluble species capable of being eluted from a coating to form minute openings or interstices in the barrier membrane to enhance diffusion through the coating." (Impax Opening Br. at 35.) The central

disputes between the parties over this term are: (1) whether the "pore-forming material" that the invention must be "free of" must be "particulate" (Biovail's position), (2) whether "pores" should be further defined as "minute openings or interstices in the barrier membrane" (Impax's position) and (3) whether the additional phrase "to enhance diffusion through the coating" is necessary (Impax's position).

The word "particulate" appears nowhere in the '341 patent. However, Biovail supports its assertion that the "pore forming material" must be "particulate" by pointing to two prior art references cited in the "Background of the Invention" section of the '341 patent, U.S. Pat. No. 4,687,660 ("the '660 patent") and European Published Patent Application No. EP-A-0171457 ("the '457 application"), as well as to U.S. Pat. No. 4,769,027 ("the '027 patent"), which was discussed in the '341 patent's prosecution history. According to Biovail, because the patentee referred to these prior art references in the specification and prosecution history in connection with the term "pore-forming agent," and because they involve pore-forming material that is particulate, one skilled in the art would look to these references to determine that "pore-forming agent" necessarily means a particulate substance. It is true that "prior art cited in a patent or cited in the prosecution history of the patent constitutes intrinsic evidence," which a court can consider along with the patent's claims themselves, the specification, and the prosecution history in defining a claim term. Kumar v. Ovonic Battery Co., Inc., 351 F.3d 1364, 1368 (Fed. Cir. 2003). However, the prior art references on which Biovail relies do not provide *definitions* of the term "pore-forming agent," but merely limit the type of pore-forming material to be used in their respective inventions. For instance, the '660 patent and the '027 patent both involve a pore-forming agent and state that "the pore-forming agent must be particulate in nature, with a

maximum particle size preferably not exceeding about 500 μm . . . ." ('660 patent, Col. 4, lns. 28-30; '027 patent, col. 4, lns. 62-64.) Similarly, the '457 application states that "[t]he particulate water-soluble pore-forming material of use in the composition of the present invention, preferably, has a maximum particle size not exceeding 500 μm . . . ." ('457 application at 5, ¶ 2.) This is the language of limitation, not definition. Moreover, as Impax points out, the fact that the adjective "particulate" is used to modify "pore-forming material" in the '457 application would seem to indicate that in general, pore-forming agent may be either particulate or non-particulate.[20]

Furthermore, to conclude that the pore-forming agent must be "particulate" would be to say that a tablet need not actually be "free of pore-forming agent" to fall within the scope of claim 30. Under Biovail's proposed construction, claim 30 covers tablets that are *not* free of pore-forming agent, so long as the pore-forming agent they include is not particulate in nature. The patentee knew how to include express limitations on what could be considered "pore-forming agent" for purposes of the '341 patent: for instance, he noted that the tablet's semi-permeable release coating was to be "free of (monomeric) pore-forming agent." (Col. 1, ln. 58.) The Anchen court, agreeing with Biovail that "free of pore-forming agent" as used in the '341 patent did not mean free of *polymeric* pore-forming agent, noted that "it is difficult to believe that one skilled in [the] art reading the patent would not give particular weight to the statement that the invention was 'free of (monomeric) pore-forming agent." Anchen, at 18. In the absence of a similarly express statement that "pore-forming agent" is limited to "particulate" matter, I must

[20] Biovail agrees that "pore-forming agent" and "pore-forming material" are used interchangeably in these prior art references. (Biovail Resp. Br. at 25.)

give the phrase "free of pore-forming agent" its ordinary and accustomed meaning. As noted above, the ordinary English meaning of the phrase "free of" is simply "not having or using" or "lacking." Webster's at 905.

With respect to polymeric pore-forming agent, it can be said that the patentee acted as his own lexicographer in the specification, explicitly carving out polymeric water-soluble species from the definition of "pore-forming agent." The same cannot be said with respect to non-particulate pore-forming agent. Thus, I reject Biovail's argument insofar as it would interpret the '341 patent to cover tablets containing monomeric pore-forming agents so long as these pore-forming agents are not "particulate," contrary to the specification's directive that the invention described in claim 30 is free of pore-forming agent. However, I also reject Impax's attempts to add elements to the definition of "free of pore-forming agent" that are not reflected in the intrinsic evidence. The '341 patent speaks nowhere of a "barrier membrane," nor does it define "pore-forming agent" as a substance meant "to enhance diffusion through the coating."

Finally, as with "stabilizer," I see no reason to deviate from the ordinary and accustomed meaning of "pore." Biovail faults Impax for relying on dictionary definitions of "pore," but does not suggest its own definition of the word. Because I do not believe the term "pore" is entirely self-defining in this context, I turn to technical and general dictionaries for insight into the term's ordinary and accustomed meaning. See Vitronics, 90 F.3d at 1584 n.6 (court "may . . . rely on dictionary definitions when construing claim terms, so long as the dictionary definition does not contradict any definition found in or ascertained by a reading of the patent documents"). Hawley's Chemical Dictionary provides, as one definition of "pore": "A void or interstice between particles of a solid such as sand minerals or powdered metals, that permits passage of

liquids or gases through the material in either direction." Hawley's at 910. As "void" and "interstice" are somewhat nebulous ways of defining "pore," I turn also to Webster's Dictionary, which provides, as one meaning of "pore," "a minute opening . . . by which matter passes through a membrane." Webster's at 1766.

I therefore adopt a modified version of Impax's proposed construction of "free of pore-forming agent," a similar version of which was approved by the Central District of California in the Anchen litigation: "lacking a monomeric water-soluble species capable of being eluted from a coating to form minute openings that permit the passage of liquids or gases in either direction."

D. *"Dissolution Profile"*

Finally, the parties disagree on whether "dissolution profile" in claims 1 and 30 is capable of being construed at all. Biovail asserts that "dissolution profile" means "a quality control assay conducted according to guidance and instructions found in the United States Pharmacopoeia, *i.e.*, the ranges of bupropion hydrochloride released after one hour, four hours, six hours and eight hours as determined by a dissolution study conducted according to guidance and instructions found in the United States Pharmacopoeia." (Biovail Opening Br. at 4.)

Impax, on the other hand, claims that "dissolution profile" is fatally indefinite and that I should delay construing it until after both sides have briefed invalidity. Impax argues that no part of the '341 patent directs the reader to the United States Pharmacopoeia (USP). In the alternative, Impax claims that even if one skilled in the art would know to look to the USP for guidance, the USP itself provides more than one potential method for determining the dissolution profile of a bupropion hydrochloride tablet, each of which leads to different results.

As Impax recognizes, at this early stage of the litigation, it would be premature for me to

conclude that the term "dissolution profile" renders the '341 patent invalid for indefiniteness under 35 U.S.C. § 112 ¶ 2. "[W]hen a claim is not insolubly ambiguous, it is not invalid for indefiniteness." Energizer Holdings, Inc. v. Int'l Trade Comm'n, 435 F.3d 1366, 1370 (Fed. Cir. 2006) (citations omitted); see also Bancorp Servs., L.L.C. v. Hartford Life Ins. Co., 359 F.3d 1367, 1371 (Fed. Cir. 2004) ("We have held that a claim is not indefinite merely because it poses a difficult issue of claim construction; if the claim is subject to construction, i.e., it is not insolubly ambiguous, it is not invalid for indefiniteness."). The parties have not yet briefed any issues pertaining to invalidity, and the Federal Circuit has "certainly not endorsed a regime in which validity analysis is a regular component of claim construction." Phillips, 415 F.3d at 1327. However, I do not find it necessary or appropriate to delay construing "dissolution profile" until after briefing on invalidity. The parties are entitled to my construction of this term as they brief invalidity and infringement issues. In any event, my construction of the term "dissolution profile" is without prejudice for the parties to request reconsideration at a later stage of the litigation. "[D]istrict courts may engage in rolling claim construction, in which the court revisits and alters its interpretation of the claim terms as its understanding of the technology evolves." Pfizer, Inc. v. Teva Pharm., USA, Inc., 429 F.3d 1364, 1377 (Fed. Cir. 2005) (citations omitted).

Because Impax has not proposed an alternative construction, I adopt Biovail's proposed construction of "dissolution profile," a nearly identical version of which was approved by the Anchen court: "A quality control assay conducted according to guidance and instructions found in the United States Pharmacopoeia, *i.e.*, the ranges of bupropion hydrochloride released after one hour, four hours, six hours and eight hours as determined by a dissolution study conducted according to guidance and instructions found in the United States Pharmacopoeia." In adopting

Biovail's proposed construction in that case, the court noted that "one skilled in the art would look to the USP to determine the parameters to be used in conducting a dissolution test." I agree with this assessment of how one skilled in the art would understand "dissolution profile" in the '341 patent, and save for another day the question of whether the USP resolves the ambiguity in the claim term sufficiently to satisfy the claim definiteness requirement of 35 U.S.C. § 112 ¶ 2.

IV. CONCLUSION

For the foregoing reasons, I construe the claim terms at issue in the '341 patent as stated in the accompanying Order.[21]

[21] Of course, I may revisit this claim construction as my understanding of the technology evolves. Pfizer, 429 F.3d at 1377.

ORDER

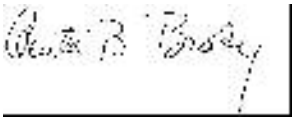
AND NOW, this __23rd___ day of May, 2006, it is **ORDERED** that the Court construes the disputed claim terms in U.S. Patent No. 6,096,341 ("the '341 patent") as follows:

(1) "delayed release tablet" means "a tablet comprising a core which includes bupropion hydrochloride and conventional excipients and a coating designed to achieve a controlled release of bupropion hydrochloride, said coating comprising a water-insoluble, water-permeable film-forming polymer, together with a plasticizer and a water-soluble polymer";

(2) "free of stabilizer" means "lacking any substance or agent that tends to prevent bupropion hydrochloride from changing its form or chemical nature";

(3) "free of pore-forming agent" means "lacking a monomeric water-soluble species capable of being eluted from a coating to form minute openings that permit the passage of liquids or gases in either direction"; and

(4) "dissolution profile" means "a quality control assay conducted according to guidance and instructions found in the United States Pharmacopoeia, *i.e.*, the ranges of bupropion hydrochloride released after one hour, four hours, six hours and eight hours as determined by a dissolution study conducted according to guidance and instructions found in the United States Pharmacopoeia."



ANITA B. BRODY, J.

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